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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,744	09/29/2006	Akira Amano	66057(71526)	3799
21874	7590	07/06/2009	EXAMINER	
EDWARDS ANELI, PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			KOSACK, JOSEPH R	
ART UNIT	PAPER NUMBER			
			1626	
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			07/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,744	<b>Applicant(s)</b> AMANO ET AL.
	<b>Examiner</b> Joseph R. Kosack	<b>Art Unit</b> 1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 April 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 2-18 is/are pending in the application.  
 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.  
 5) Claim(s) 16 is/are allowed.  
 6) Claim(s) 2-7 is/are rejected.  
 7) Claim(s) 17 and 18 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/0256/06)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 2-18 are pending in the instant application.

#### ***Amendments***

The amendment filed on April 13, 2009 has been acknowledged and has been entered into the instant application file.

#### ***Previous Claim Rejections - 35 USC § 102***

Claims 1-7 were previously rejected under 35 U.S.C. 102(b) as being anticipated by Jennerwein et al. (*J. Cancer Res Clin Oncol*, 1988, 347-358).

The Applicant has deleted the anticipated subject matter, and the rejection is withdrawn.

#### ***Claim Objections***

Claims 17 and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims contain metal salts in which m from claims 3 and 6 would be 1, where in claims 3 and 6 m can only be 2 or 3. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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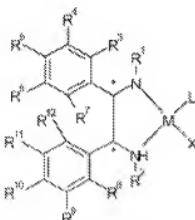
Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds where L is an  $\eta^6$ -benzene, does not reasonably provide enablement for any other ligands. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

*The Nature of the Invention*

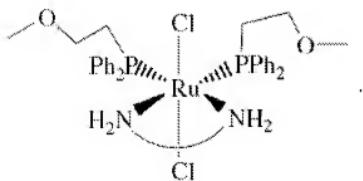
The nature of the invention is compounds and catalysts made from reacting a chiral diamine with a metal salt which yields a complex of the formula



, where M is ruthenium, rhodium, or iridium; L is a ligand, X is a halogen, and at least one of R3-R7 and R8-R12 is a substituted amino group.

The State of the Prior Art and the Predictability or Lack Thereof in the Art

The prior art on ruthenium, rhodium, or iridium complexes with a chiral diamine is such that the metal center can have 4 ligand binding sites or 6 ligand binding sites. One example of a complex with 4 ligand binding sites is Hashiguchi et al. (*Journal of the American Chemical Society*, 117, 7562-7563) teach a complex with an  $\eta^6$ -benzene as the ligand with a chiral diamine and a halogen. However, if the ligand is changed to a two-electron donor such as a phosphine as shown by Warad et al. (*Inorganica Chimica Acta*, 2004, 1847-1853), the metal center has 6 ligand binding sites:



. See compound 1L4 on page 1848.

Therefore, the Applicant cannot guarantee that using any available ligand will generate a 4-coordinate complex as required by claims 2-7.

It is essential in the art that knowledge of the production of related compounds be available to establish the predictability of the production of a new compound. Since there is no prior art that details the claimed compound or related compounds or the production of such compounds, there is a severe lack of predictability in the production of the claimed compound by one of ordinary skill.

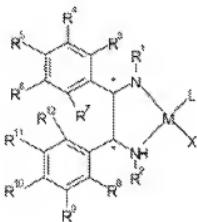
The Amount of Direction or Guidance Present and the Presence or Absence of Working

Examples

The specification provides a method of making the complexes which is the same as claim 3 of the instant claim sets, but the examples do not provide any isolated complexes in order to show whether the complexes are 4 or 6 coordinate.

*The Breadth of the Claims*

The breadth of the claims is compounds and catalysts made from reacting a chiral diamine with a metal salt which yields a complex of the formula



, where M is ruthenium, rhodium, or iridium; L is a ligand, X is a halogen, and at least one of R3-R7 and R8-R12 is a substituted amino group.

*The Quantity of Experimentation Needed*

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine all of the reagents, reaction conditions and synthetic schemes in order to make and use the claimed compounds where the ligand is not  $\eta^6$ -benzene.

*The Level of Skill in the Art*

The level of skill in the art of organometallic synthesis is high. However, due to the unpredictability in the art as described above, one of ordinary skill would be unable to make or use the claimed compound without undue experimentation in order to practice the invention as claimed.

Thus, the specification fails to provide sufficient support of the preparation and use of complexes of formula 2 and claims 2-7 where the ligand is not an  $\eta^6$ -benzene. As a result, the application would require one of skill to perform an exhaustive search and an inordinate number of experiments in order to make or use the claimed compound.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated by the compound encompassed in the instant claims, with no assurance of success.

#### ***Conclusion***

Claims 2-7 are rejected. Claims 17 and 18 are objected to. Claim 16 is currently allowable over the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph R. Kosack whose telephone number is (571)272-5575. The examiner can normally be reached on M-Th 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joseph R Kosack/  
Examiner, Art Unit 1626